

Remarks

The present invention relates to methods of using novel truncated GDNF proteins to promote dopamine uptake by dopaminergic neurons and support the survival of the neurons that die in Parkinson's Disease. Claims 30 and 45-50 are currently pending in the present application. Claims 30 and 45-50 are subject to restriction. In the restriction requirement, the Examiner divided the pending claims into the following groups:

| <u>Group</u> | <u>Claims</u> | <u>Subject Matter</u> |
|--------------|---------------|---|
| I | 30 and 45-50 | A method for affecting survival or function of neurons comprising administering a GDNF protein product consisting of the amino acid sequence of SEQ ID NO:42. |
| II | 30 and 45-50 | A method for affecting survival or function of neurons comprising administering a GDNF protein product consisting of the amino acid sequence of SEQ ID NO:44. |
| III | 30 and 45-50 | A method for affecting survival or function of neurons comprising administering a GDNF protein product consisting of the amino acid sequence of SEQ ID NO:46. |

The Restriction Requirement required election of one of the above groups under 35 U.S.C. § 121. Applicants have elected Group I with traverse.

Traverse of the restriction requirement turns on the issue as to whether there would be a serious burden on the Examiner if restriction was not required. 35 U.S.C. §121 states that "[i]f two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions (emphasis added)." The statute, therefore, establishes restriction as a procedural matter within the discretion of the Patent and Trademark Office Director. M.P.E.P. § 803 provides Examiners with further guidance as to when restriction is proper. Section 803 states "[i]f the search and examination of an entire application can be made without serious burden, the examiner **must** examine it on the merits, even though it includes claims to independent or distinct inventions (emphasis added)."

The Examiner indicated that the restriction was proper because "[e]ach of SEQ ID NOS: 42, 44, and 46 is a unique sequence requiring a unique search of the prior art. Searching all of the

sequences in a single patent application would provide an undue search burden on the examiner and the USPTO's resources because of the non-coextensive nature of these searches (Paper No. 6, page 2)."

Applicants respectfully traverse the Restriction Requirement and request reconsideration and/or withdrawal thereof. Applicants contend that it would not be a serious burden on the Patent Office if restriction is not required amongst the groups identified in the present Office Action because of the similarity between the various polypeptide sequences recited. Teachings on this type of closely related subject matter are readily identified with sequence based searches. The advanced state of bioinformatics and indexed sequence databases presently allows such searches to be rendered without unduly burdening the searching authority. A single well thought out search using any one of the closely related, albeit unique, sequences (SEQ ID NO:42, 44, and 46) would be sufficient to identify the closest matching polypeptides known in the art. In the present case, multiple searches of divergent fields would not be necessary for a thorough examination. The oddity of requiring a restriction in the present case is becomes apparent when it is considered that regardless of the Group selected, the same claims end up being prosecuted in the present case. On these facts, Applicants respectfully submit that the Examiner has failed to validly establish a prima facie case for restriction and has improperly restricted inventive subject matter into the groups shown above.

In conclusion, Applicants assert that the Examiner did not set forth reasons sufficient to impose the present restriction requirement on the present application. Therefore, Applicants respectfully traverse the Restriction Requirement and request reconsideration and/or withdrawal thereof. So as to be fully responsive to the Restriction Requirement, Applicants hereby provisionally elect, with traverse, the invention of Group I (Claims 30 and 45-50). In addition, Applicants hereby elect the species of Claim 45 wherein X is SEQ ID NO:18.

Respectfully submitted,



Robert L. Sharp
Attorney for Applicants
Registration No.: 45,609
Phone: (805) 447-5992
Date: August 2, 2002

Please send all future correspondence to:
U.S. Patent Operations/RLS
Dept. 4300, M/S 27-4-A
AMGEN INC.
One Amgen Center Drive
Thousand Oaks, California 91320-1799